REMARKS

Claims 24-30, 32-33, and 35-48 are pending in this Application. Claims 24-30, 32-33, and 35-48 have been rejected. Claims 24, 28, 41, 46 and 47 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Withdrawn Rejections

Applicants acknowledge the withdrawal of the rejection of claim 24 under 35 U.S.C. 112, second paragraph; the withdrawal of the rejection of claims 24-31, 35, 38, 40-43 and 45-48 under 35 U.S.C. 102(b) as being anticipated by Price et al. (US 4,128,658); the withdrawal of the rejection of claims 24-25, 28-30, 35-36 and 45-47 under 35 U.S.C. 102(b) as being anticipated by Fuisz (US 5,387,431); and the withdrawal of the rejection of claims 32-33, 36-37, 39 and 44 under 35 U.S.C. 103(a) as being unpatentable over Price et al. (US 4,128,658) in view of Santus et al. (US 5,472,704).

II. Rejections Under 35 U.S.C. §103

Claims 24-30, 35, 38, 40-43 and 45-48 have been newly rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (US 4,128,658) in view of Fuisz (US 5,387,431). At pages 4 and 5 of the Office Action, the Examiner suggests that Price teaches a method of producing oral sustained release tablets by mixing an active ingredient, anhydrous lactose and Cutina HR; moistening the mixture by mixing with a 10% solution of Cutina HR; granulating the moistened mass through a 1.2 mm aperture sieve; and drying at 50°C in a bed dryer. It is suggested that Price teaches that the granules

are then passed through a 0.85 mm aperture sieve, blended with the magnesium stearate and compressed on a tableting machine with 12.5 mm diameter punches. The Examiner concludes that because the drug is dissolved in water, it is hydrophilic. It is acknowledged that Price does not expressly teach an oily substance selected from the group specified in the claims. However, it is suggested that Fuisz teaches a method of preparing a substantially solid saccharide-based matrix comprising subjecting a feedstock comprising a mixture of solid maltodextrin and an oleaginous material, such as corn oil, to conditions of force and temperature and using the same in the preparation of pharmaceutical materials containing vitamins, acetaminophen and sucralfate. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of producing granules as suggested by Price and substitute the hydrogenated castor oil with the corn oil of Fuisz and produce the instant invention.

Applicants respectfully disagree with this rejection. Applicants assert that the combination of Price and Fuisz fails to teach the present invention. As the instant Specification indicates at page 4, ¶5, processing active ingredients that are corrosive to metal can be challenging. Applicants have appreciated that processing of such corrosive active ingredients can be facilitated in the presence of an oily substance. Accordingly, in an earnest effort to highlight this feature, Applicants have amended base claims 24, 41 and 46 to indicate that the active ingredient is corrosive. Support for this amendment is found at page 4, ¶5 of the instant specification In so far as

further support for this amendment is found in claims 28 and 47, these claims have been amended to remove reference to the term corrosive.

In this respect, neither of the cited references teach, suggest nor appreciate metal corrosive active ingredients as a problem in producing granules for a pharmaceutical formulation. While the Examiner contends that Price discloses a composition comprising a hydrophilic drug with an oily substance (a 10% solution of Cutina HR), there is no teaching in Price to suggest the combination of an oily substance with a corrosive active ingredient, and clearly no teaching of the advantage that such a combination would provide. Furthermore, although Fuisz refers to the use of corn oil in one example, this reference does not describe the use of corn oil in combination with a corrosive active ingredient. Moreover, while Fuisz provides a list of possible active ingredients of use therein (col. 6-7), Fuisz does not require the presence of corn oil or any other oily substance. Indeed, the invention of Fuisz relates to a "saccharide based matrix" such that one skilled in the art would not reasonably conclude that an oily substance must also be present in the composition of Fuisz containing one of the active ingredients at col. 6 and 7.

Without the insight provided by the instant specification, there would be no rationale to combine a corrosive active ingredient with an oily substance as claimed. To simply combine the teachings of Price and Fuisz without considering the effect to be achieved, in this case the protection of equipment, the rejection falls into the first error identified in *O'Farrell*, in which "what would have been 'obvious to try' would have been to vary all

parameters or try each of number possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). As upheld in *Abbott Laboratories v. Sandoz, Inc.* (Fed. Cir. 2007), "the obviousness of selection of components, when there is no prediction in the prior art as to the results obtainable from a selected component, differs from the issue in *KSR*, where the Court provided guidance that 'a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.'" 127 S. Ct. at 1740.

In this respect, Applicants assert that the present invention cannot be viewed as a predictable result of combining or substituting single elements known from the prior art documents of Price or Fuisz because it was not known prior to the present invention that the combination of claimed elements protect equipment from damage by corrosive active ingredients. Indeed, in view of the large number of possible elements in pharmaceutical compositions, including the vast number of active ingredients and infinite number of excipients, carriers and the like, Applicants respectfully assert that there would be no reasonable expectation of successfully obtaining the claimed method by varying all the parameters of a pharmaceutical composition to arrive at those presently claimed.

The Examiner's broad-brush approach and unfounded assumptions were condemned in *Graham v. John Deere Co.*, where it was recognized that the obviousness inquiry must

"guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." 383 U.S. at 36, 86 S.Ct. at 703. As Applicants have indicated, there are a myriad of possible elements in pharmaceutical compositions, such that the "known options" in the prior were not "finite, identified, and predictable," the words of *KSR* (550 U.S. 398 (2007)). Only with the Applicants' educated application of what was known in the art and intelligent exploration of what was not known did Applicants appreciate the benefit of including an oily substance as presently claimed in the preparation of a pharmaceutical composition containing a corrosive active ingredient. Accordingly, the present invention cannot be held obvious and it is respectfully requested that this rejection be reconsidered and withdrawn.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515
Email: jmlicata@licataandtyrrell.com